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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,687	10/05/2000	Stephen M. Allen	BB1162 US NA	1467
27123	7590	02/04/2005	EXAMINER	
MORGAN & FINNEGAN, L.L.P.			HUNNICUTT, RACHEL KAPUST	
3 WORLD FINANCIAL CENTER			ART UNIT	
NEW YORK, NY 10281-2101			PAPER NUMBER	

1647

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/679,687

Applicant(s)

ALLEN ET AL.

Examiner

Rachel K. Hunnicutt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-30, 32 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-30, 32 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. This application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid. The Information Disclosure Statement, mailed 19 October 2004, has been entered into the record.

Claims 25-30, 32 and 34 are under consideration.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 32 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 32 recites "a cell comprising", which encompasses the host cell, as it occurs in nature, for example, as a gene therapy patient. However, since Applicants do not intend to claim a naturally occurring product, amendment of the claim to show the hand of man would obviate this rejection. It is suggested that claim 32 be amended to recite "an isolated cell" or "a purified cell". Appropriate correction is required.

Claims 25-30, 32 and 34 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 25-30, 32, and 34 are directed to isolated polynucleotides encoding polypeptides comprising SEQ ID NO: 2 and polynucleotides comprising SEQ ID NO: 1. The specification asserts that the polypeptide encoded by SEQ ID NO: 2 is a sucrose-transport polypeptide. The claimed polynucleotide is not supported by either a specific and substantial asserted utility or a well-established utility.

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A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" use for the claimed invention. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966):

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

Uses such as producing variants or chimeric nucleotides or polypeptides, producing hybridization probes and primers for the detection of nucleic acid molecules, creating transgenic organisms, and detecting homologs in other species are useful only in research to determine the function of the encoded protein itself. Further, the specification does not disclose specific cDNA, DNA, or RNA targets. There is no "specific benefit in currently available form" to be derived from such studies. Further, while Applicants assert that the claimed polynucleotides can be used for gene therapy, the specification does not disclose conditions associated with a mutated, deleted, or translocated gene of the claimed invention. Significant further experimentation would be required of the skilled artisan to identify organisms with such a condition and to determine the route of administration of the gene, as well as quantity and duration of treatment. Merely listing a number of possibilities is not sufficient to identify or confirm a "real world" context of use; clearly further research would be required to identify a disease in which the encoded protein is involved. Thus, significant further research is required to identify a disease for which it could be used, or a disease for which its presence would be diagnostic. See *Brenner v. Manson*, noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." A patent is therefore not a license to experiment.

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and credible utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. The specification fails to assert any activity for the encoded polypeptide other than those generally recognized to be attributes of sucrose transporters. The Specification and Applicant's response (20 October 2004) assert that the claimed polynucleotide encodes a sucrose transporter protein based on homology to known

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transporters (Aoki, *et al.*, 1999, *Plant Cell Physiol.*, 40(10): 1072-1078; Aoki, N., 2003, Accession No. BAA83501). Identifying a nucleic acid molecule as encoding a sucrose transporter does not endow the nucleic acid molecule with a specific and substantial utility. The art shows that structurally similar transporters are unpredictably *functionally* dissimilar. For example, relevant literature reports that sugar transporters constitute a diverse class of enzymes with respect to kinetic properties, regulation, pharmacology, and structure (see, for example: Bisson, *et al.*, 1993, *Crit. Rev. Biochem. Mol. Biol.* 28 (4): 259-308). Sugar transporters are involved in the control of a variety of significant physiological functions, including feeding, excretion, and reuptake of critical small molecules.

Although transporter family members share several common structural features, relevant art (Bisson, *et al.*, 1993, *Crit. Rev. Biochem. Mol. Biol.* 28 (4): 259-308) shows that members of a class do not always share a specific and substantial functional attribute or utility, despite having structural features in common. Mutations in transporters serve to illustrate this fact, since a single amino acid substitution can change the substrate specificity of a transporter or inactivate it. For example, several single amino acid substitutions in a yeast glucose transporter can change substrate specificity (Liang, H., *et al.* (1998) *Mol. Cell. Biol.* 18(2): 926). Similarly, point mutations in a nucleoside transporter have been shown to alter substrate specificity such that the mutant transporter bears similarity to P-glycoprotein or the Multi-drug Resistance transporter (Vasudevan, *et al.* (2001) *Mol. PNAS* 98(11): 6092-6097). These examples serve to illustrate that membership in a class of transporters may not impart a specific or substantial utility to a new member, such as the claimed polynucleotide of the Instant Application. There is therefore no well-established utility for members of this family; utility is specific to the individual protein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-30, 32 and 34 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

NO CLAIMS ARE ALLOWED.

The following articles, patents, and published patent applications were found by the Examiner during the art search while not relied upon are considered pertinent to the instant application:

Hainey *et al.*, NCBI Accession No. AY106212, zeamays PC0103031 mRNA sequence, October 16, 2002. The sequence is 100% identical to SEQ ID NO: 1.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
2/3/05


JANET ANDRES
PRIMARY EXAMINER